C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

K002868

M3

DEC - 8 2000

BARD

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Submitter's Address:	8195 Industrial Blvd., Covington, GA 30014
Contact Person's Telephone Number:	770-784-6774
Contact Person's FAX Number:	770-784-6419
Date of Preparation:	September 8, 2000

B. Device Name:

Bardex® All-Silicone 3-way Foley Catheter
Bardex® Lubri-Sil™ 3-way Foley Catheter
Bardex® Lubri-Sil™ I.C. 3-way Foley Catheter

C. Predicate Device Name:

Bardex® Lubri-Sil™ Foley Catheter
Bardex® Lubri-Sil™ I.C. Foley Catheter
Bardex® All-Silicone Foley Catheter
Bardex® Lubricath® Foley Catheter

D. Device Description

The Bardex® All-Silicone 3-way Foley Catheter is a three-way all-silicone Foley catheter.

The Bardex® Lubri-Sil™ 3-way Foley Catheter is a three-way all-silicone Foley catheter with a lubricious hydrophilic coating.

The Bardex® Lubri-Sil™ I.C. 3-way Foley Catheter is a three-way all-silicone Foley catheter with silver and lubricious hydrophilic coatings.

E. Intended Use:

The Bardex® All-Silicone 3-way Foley Catheter, the Bardex® Lubri-Sil™ 3-way Foley Catheter, and the Bardex® Lubri-Sil™ I.C. 3-way Foley Catheter are indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.

Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

F. Technological Characteristics Summary:

The Bardex® All-Silicone 3-way Foley Catheter, the Bardex® Lubri-Sil 3-way Foley Catheter, and the Bardex® Lubri-Sil I. C. 3-way Foley Catheter are constructed of a high grade extruded clear silicone rubber with a bonded tip and funnel. Each is a three-lumen catheter with a drainage lumen, an inflation/deflation lumen with two-way valve and an irrigation lumen.

For the Lubri-Sil 3-way Foley Catheter a hydrophilic polymeric coating is applied to the finished catheter. This coating becomes very slippery when wet. The Lubri-Sil 3-way Foley Catheter is available in even shaft sizes 16-24 Fr. with a 5cc balloon and a 30cc balloon.

For the Lubri-Sil I. C. 3-way Foley Catheter a silver coating and then a hydrophilic polymeric coating are applied to the finished catheter. The hydrophilic coating becomes very slippery when wet. The silver coating discourages bacterial adhesion to the catheter surface. The Lubri-Sil I.C. 3-way Foley Catheter is available in even shaft sizes 16-24 Fr. with a 5cc balloon and a 30cc balloon.

G. Performance Data:

The All-Silicone 3-way Foley Catheter, the Lubri-Sil 3-way Foley Catheter, and the Lubri-Sil I. C. 3-way Foley Catheter meet the following performance requirements per testing conducted according to ASTM F623-89, when appropriate, and/or Bard testing/acceptance criteria:

Note: ASTM F623-89 is applicable only to bi-lumen (2-way) catheters, however, the test methods described therein will be utilized to test tri-lumen (3-way) catheters.

- Flow Rate
- Balloon Integrity
- Balloon Response to Pullout
- Balloon Volume Maintenance
- Manufacturing Tolerances for Catheter Tip, Balloon and Shaft Diameters
- Balloon Deflation Reliability
- Coefficient of Friction

- Balloon Burst Volume
- Foley Catheter Shaft Break Strength
- Foley Catheter Tip Adherence
- Elution Studies

Testing on aged product indicates that application of the coatings have no adverse effect on the base material of the shaft or balloon.

Testing for bacterial adherence demonstrates that there is significantly less bacterial adherence to the Lubri-Sil I.C. 3-way Foley Catheter surface than to an uncoated silicone catheter surface. Bacterial adherence to the Lubri-Sil I.C. 3-way Foley Catheter was similar to that for the Lubri-Sil I.C. 2-way Foley Catheter. Clinical isolates used in the bacterial adherence testing included: Candida albicans, Citrobacter diversus, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and Staphylococcus saprophyticus.

Biocompatibility testing was based upon ISO 10993-1 requirements for surface devices contacting mucosal membranes for prolonged contact duration. In order to present a worst case scenario, the samples for biocompatibility testing were prepared with a silver concentration at or near the high end of the process range (approximately 4.0 $\mu g/cm^2$).

The biocompatibility testing described above was conducted on the Lubri-Sil I.C. 2-way Foley Catheter with radiopaque stripe model, size 22 Fr., using uncoated silicone catheters as a control where appropriate, or a previously determined specification or standard.

The Lubri-Sil I.C. 2-way Foley Catheter with radiopaque stripe was selected as a worse case scenario, but the results are applicable to the 3-way catheters subject of this submission because both catheter models are constructed of the same materials and manufactured under the same conditions. The silver and hydrogel coating is the same on both models and was chosen as representative of all three models (uncoated, lubricous-coated and silver/hydrogel coated) because it represents the worst case scenario. For biocompatibility testing, the design differences are meaningless.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 8 2000

Ms. Angela L. Bunn
Regulatory Affairs Associate
C. R. Bard, Incorporated
8195 Industrial Boulevard
Covington, GA 30014

Re: K002868
Bardex® All-Silicone 3-way Foley Catheter, Bardex® Lubri-Sil™ 3-Way Foley Catheter and the Bardex® Lubri-Sil™ I.C. 3-Way Foley Catheter
Dated: September 8, 2000
Received: September 13, 2000
Regulatory Class: II
21 CFR §876.5130/Procodes: 78 EZL and MJC

Dear Ms. Bunn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

SECTION I - D

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002868

Device Name: Bardex® All-Silicone 3-way Foley Catheter, Bardex® Lubri-Sil™ 3-way Foley Catheter and the Bardex® Lubri-Sil™ I.C. 3-way Foley Catheter

Indications for Use:

The Bardex® All-Silicone 3-way Foley Catheter, the Bardex® Lubri-Sil™ 3-way Foley Catheter and the Bardex® Lubri-Sil™ I.C. 3-way Foley Catheter are indicated for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.

Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

David G. Segura

(Division Sign-Off)
Division of Abdominal, ENT,
and Radiological Devices
510(k) Number K002868